



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC - 9 1998 6 '98 DEC 18 NO :27

Ms. Bella Bomze
T-UP Biosystems, Inc.
Neptune Retail Station
P.O. Box 245388
Brooklyn, New York 11224

Dear Ms. Bomze:

This is in response to your letter of December 3, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that T-UP Biosystems, Inc. is marketing the dietary supplement "Fiber Max" labeled with the claim, among others, that "Calcium helps teens and young adult Caucasian and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life (it is recommended to add regular exercise and a healthy diet)."

This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a claim subject to section 21 U.S.C. 343(r)(1)(B) for which FDA has authorized a health claim under 21 U.S.C. 343(r)(5)(D) (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#62638)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

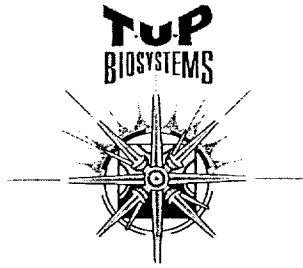
HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:HFS-456:rjm:12/9/98:docname:62638.adv:disc33

Neptune Retail Station
P.O. Box 245388
Brooklyn, NY 11224

Immune Enhancement Programs



Fax: (718) 265-6206
Tel: (718) 265-7163

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NOTIFICATION TO THE OFFICE OF SPECIAL NUTRITIONALS

*The Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW., Washington, DC 20204*

Our company T-UP Biosystems, Inc., first started to market two new dietary supplements: Alozone-M and Fiber Max on November 14, 1998.

Alozone-M and Fiber Max bear statements listed in section 403(r)(6) containing structure and health claims. These statements included on the labels and in the labeling of these products. Therefore the required disclaimer statements are placed on the labeling of each product.

ALOZONE-M Immune Enhancer*

Alozone-M bears the following structure claim: Immune Enhancer*

**Made from highly concentrated specially grown Aloe
and organic minerals from plant sources**

Size: 2oz
Suggested dosage: One teaspoon per day in a glass of an apple juice, your favorite fruit juice or water.
Serving size: 1 teaspoon (5mL)
Serving per container: 12 teaspoons

The following disclaimer statement is used in the labeling of Alozone-M:

***This statement has not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure or prevent any disease.**

GREAT DELICIOUS FIBER MAX

GREAT DELICIOUS FIBER MAX bears the following structure claims:

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- Insoluble fibers improve regularity in our body's elimination functions.*
- Dietary fibers may also help regulate blood glucose response to meals, by avoiding the highs and lows of blood glucose peaks.*
- Dietary fiber may also reduce the feeling of hunger and prevent overeating.*
- Calcium helps teens and young adult Caucasian and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life (it is recommended to add regular exercise and a healthy diet).

High-fiber dietary supplement with vitamins and natural minerals, peach flavored.

Size: 19.7 oz
Suggested dosage: One - two scoops in a glass of apple juice, your favorite fruit juice, milk or water.
Serving size: 2 Scoop (40g)
Serving per container: 14

The following disclaimer statement is used in the labeling of Fiber Max:

*These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure or prevent any disease.

I am Bella Bomze, president of T-UP Biosystems, Inc., certifying the accuracy of the information presented and contained in this notice. To the best of my knowledge and effort the information contained in the notice is complete and accurate, and that T-UP Biosystems, Inc. has substantiation that the statements on the labeling of both products: Alozone-M and Fiber Max are truthful and not misleading.

President of T-UP Biosystems, Inc.

Bella Bomze

Bella Bomze
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Many governmental agencies and health organizations recommend that adults consume dietary soluble and insoluble fibers in their diet each day.

If you are looking for a way to lose weight by consuming a healthy and low calorie diet, T-UP Biosystems Fiber Max is it. This Fiber Max plays many important roles and it has been shown to have beneficial health effects in many areas.

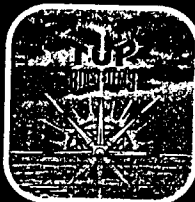
Insoluble fibers improve regularity in elimination functions. Dietary fibers may also help regulate blood glucose response to meals by avoiding the highs and lows of blood glucose peaks. Dietary fiber may also help achieve a satisfied feeling after eating and reduce a feeling of hunger for prevention of overeating. Calcium helps teens and young adults. Caucasian and Asian women maintain good bone health and they reduce their high risk of osteoporosis later in life. It is recommended to add regular exercise and a healthy diet.

T-UP Biosystems Fiber Max is a balanced source of both insoluble and soluble fibers. T-UP Biosystems Inc. uses 12 different types of plant fibers and bran which have been scientifically balanced to provide you with a rich source of natural fiber. In addition to the specially balanced mixture of fiber, T-UP Biosystems Essential Mineral Trace Element complex is added to enhance the Fiber Max with a variety of natural body minerals and trace elements which come from nature and are balanced. T-UP Biosystems Fiber Max provides fiber, vitamins, and minerals in a healthy balanced foundation.

100% pure crystalline fructose, contained in the Fiber Max, is a different kind of sugar, which causes less of a rise in blood sugar than any other sugar and less rise than from many forms of starch.

Store at room temperature in a dry place. Do not use if seal is broken. It is a good policy for all people to consult their physician before using this or any other health product.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



Flavor: PEACH

Manufactured exclusively for
T-UP Biosystems, Inc.
Neptune Retail Station
P.O. Box 245388
Brooklyn, NY 11224
Fax: (718) 265-6206

Great Delicious FIBER MAX

Fructose Sweetened



Phyto Plant High Fiber Supplement. Cholesterol Free!
Over 62 Essential Vitamins and Minerals and Trace Elements. 12 Soluble and Insoluble Fibers!
Net Weight 19.7 Ounces (560 Grams)

Supplement Facts

Serving Size 2 Scoops (40 g)
Servings Per Container 14

Amount Per Serving

Calories 130 Calories from Fat 15

	% Daily Value*
Total Fat 1.5 g	2%
Saturated Fat 0 g	0%
Cholesterol 0 mg	0%
Sodium 75 mg	3%
Potassium 190 mg	6%
Total Carbohydrate 34 g	11%
Dietary Fiber 12 g	
Soluble Fiber 7 g	
Insoluble Fiber 5 g	
Sugars 19 g	

Protein 1 g

Vitamin A (Palmitate)	3,500 IU 70%
Vitamin C (Ascorbic Acid)	12 mg 20%
Vitamin D (Cholecalciferol)	260 IU 20%
Vitamin E (Tocopheryl Acetate)	6 IU 20%
Vitamin B1 (Thiamin)	300 mcg 20%
Vitamin B2 (Riboflavin)	340 mcg 20%
Niacin (Nicotinamide)	4 mg 20%
Vit. B6 (Pyridoxine Hydrochloride)	400 mcg 20%

Directions: Take 1-2 scoops (suggested dosage 2 scoops per day) of T-UP Biosystems Fiber Max and place in a full 8 oz container of apple juice or your favorite fruit juice or water. Shake in a closed container or blend in a blender until thoroughly mixed. Add your favorite fruit to enhance flavor, as you wish. Serve immediately.

Vitamin B9 (Folate)	80 mcg 20%
Vit. B12 (Cyanocobalamin)	1.2 mcg 20%
Biotin	60 mcg 20%
Pantothenic Acid	2 mg 20%
Calcium (Phosphate)	200 mg 20%
Iron (Electrolytic)	3.6 mg 20%
Phosphorus	100 mg 10%
Iodine (Potassium Iodide)	30 mcg 20%
Magnesium (Oxide)	60 mg 15%
Zinc (Oxide)	3 mg 20%
Copper (Gluconate)	400 mcg 10%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Total Fat	Calories 2,000	2,500
Sat Fat	Less than 65 g	80 g
Cholesterol	Less than 20 g	25 g
Sodium	Less than 300 mg	300 mg
Potassium	Less than 2,400 mg	2,400 mg
Total Carbohydrate	Less than 300 g	375 g
Dietary Fiber	25 g	30 g

Calories per gram 1
Fat 9 Carbohydrates 4 Protein 4

OTHER INGREDIENTS: Crystalline Fructose, Gum Arabic, Soy Fiber, Dehydrated Peach Juice, Oat Fiber, Oat Bran Flour, High Oleic Sunflower Oil, Corn Syrup Solids, Natural and Artificial Flavors, Stabilized Rice Bran, Tricalcium Phosphate, Dipotassium Phosphate, Pea Fiber, Sugar Beet Fiber, Microcrystalline Cellulose, Potassium Citrate, Beta Carotene, Beet Juice Powder, Sodium Caseinate, Salt, Xanthan Gum, Corn Bran, Cellulose Gum, Potassium Chloride, Mono and Diglycerides, Guar Gum, Powdered Psyllium Husk, Citrus Pectin, Dicalcium Phosphate, Natural Mineral Mix, Soy Lecithin, Folic Acid.



Directions: 1-4 tsp. daily or as prescribed by your health care professional.

Ingredients: highly concentrated specially grown and processed Aloe Vera (Whole Leaf, Aloin Free) and humic shale (ore) from ancient plant source, containing 75 organic colloidal minerals in trace amounts. Other ingredients: Potassium Sorbate, Citric and Ascorbic Acids, Sodium Benzoate. No added sugar, starch, salt or yeast. Shake well before using. Do not use if seal is broken.

Bio Technology: Positive. High Structured Blend™ Formulated by the Method of Dr. V. Gouliakov MD.

It is a great tonic for all people to reach their personal health goals. It is a powerful tonic for the immune system, which gives people the ability to fight off all other harmful organisms.

Keep refrigerated after opening.

IMMUNE ENHANCER*

ALOZONE-M™

Herbal and Amino Acid Supplement

2 Fl. Oz. (59.1 mL)

Supplement Facts: Serving Size 1 tsp. (5mL), Amount Per Serving: Calories 0, Fat 0g, Total Fat 0g (0% DV), Sodium 37.5mg (1% DV), Potassium 190mg (4% DV), Chloride 18.6mg (0% DV), Total Carb 0g (0% DV), Magnesium 21.7mg (1% DV), Phosphorus 100mg (2% DV), Total Carb 0g (0% DV), Sugar 0g (0% DV), Protein 1g (2% DV).
*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured by T-UP Biosystems, Inc.
Neptune Retail Station P.O. Box 245388
Brooklyn, NY 11224 Tel. (718) 265-7163

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